**DOCKET NO.:** ISIS-1158 **Application No.:** 08/319,411

Office Action Dated: October 6, 2004

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

## **REMARKS**

Claims 53, 63, and 64 are pending. No claims are added, amended, or canceled. Based on recent amendments to the claims, Applicants submit herewith papers implementing a change of inventorship.

Applicants would like to thank the Examiner for the interview on March 3, 2005. During that interview, Applicants' attorney, Joseph Lucci, noted that the outstanding rejections for alleged obviousness-type double patenting do not satisfy the requirements of MPEP § 2144.08. As was discussed during the interview, the mere fact that a claim under examination overlaps with a claim of an issued patent is not sufficient to support an obviousness-type double patenting rejection. For example, although claims 53, 63, and 64 stand rejected for alleged obviousness-type double patenting over claim 1 of the U.S. Patent No. 5,773,571 ("the 571 patent"), the Examiner has not demonstrated that those of ordinary skill having knowledge of the claim 1 would have found the instant claims to have been obvious.

Although the Advisory Action asserts that there is overlap among the claims, no such overlap actually exists. In the instant claims, for example, each pair of A-A<sub>m</sub> and B-B<sub>m</sub> are >N-C(O)CH<sub>2</sub>-. Such a structure is possible in the context of claim 1 of the 571 patent, only if variable J is selected to be N. This selection, however, imposes two requirements that exclude the compounds of the instant claims. The first requirement is that at least one of y or z is other than 1 or 2, whereas y would have to be 1 and z would have to be 2 to embrace the instant claims. The second requirement is that at least one linking group is of formula >N-[CR<sup>1</sup>R<sup>2</sup>]<sub>r</sub>-Y-[CR<sup>1</sup>R<sup>2</sup>]<sub>s</sub>-NR<sup>3</sup>-C(=X)-, which does not include >N-C(O)CH<sub>2</sub>- in its scope. (See claim 1 at column 91, line 45 to column 92, line 5).

Even if there were overlap, the MPEP cautions that this still would provide inadequate support for an obviousness-type double patenting rejection. MPEP § 2144.08, for example, states that "[t]he fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." MPEP § 2144.08, II.<sup>1</sup> Rather, there must be a teaching that would have motivated one of ordinary skill in the

As will be recognized, the analytic approach employed in connection with an obviousness-type double patenting determination parallels that employed in connection with a 35 U.S.C. § 103 obviousness determination. *In re Braat*, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991.

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art to make a claimed compound based on claim 1 of the 571 patent. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2D (BNA) 1596, 1598 (Fed. Cir. 1988) (obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.). Since no such teaching has been identified, Applicants request reconsideration and withdrawal of the rejection.

Claims 53 and 63 stand rejected for alleged obviousness-type double patenting in view of overlap with claims 1 and 12 of U.S. Patent No. 6,613,873 ("the 873 patent"). As noted above with reference to the 571 patent, however, mere overlap is insufficient to support the rejection. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 53, 63, and 64 also stand rejected for allegedly obviousness-type double patenting over claims 1, 4, 5, and 7 of U.S. Patent No. 6,395,474. Although Applicants do not necessarily concur, Applicants agree to submit a terminal disclaimer once otherwise allowable subject matter is indicated.

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In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (215) 568-3100 if there are any questions regarding Applicants' claimed invention.

Respectfully submitted,

Date: March 17, 2005

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